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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

UNDERDAHL, THANE E

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/826,585	<b>Applicant(s)</b> O'HARA ET AL.	
	<b>Examiner</b> Thane Underdahl	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-186 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-186 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

The examiner objects to the claims received on 4/16/2004. The claim numbering is not sequential and claim numbers are missing. In particular see claim 148 and claims 158-160. Please make the appropriate corrections.

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-50 are drawn to a method of extracting intact cytoplasmic biomolecules, classified in class 435, subclass 183.
  - II. Claims 51-64 are drawn to a method of improving signal-to-noise detection of distinct target species, classified in class 435, subclass 6.
  - III. Claims 65-82 are drawn to a method of acquiring intact cytoplasmic biomolecules from cells, classified in class 435, subclass 183.
  - IV. Claims 83-91 are drawn to a method for amplifying multiple genetic markers in the same reaction mix, classified in class 435, subclass 91.2.
  - V. Claims 92-134 are drawn to an apparatus for extraction of cytoplasmic biomolecules from cells, classified in class 435, subclass 183.
  - VI. Claims 135-150 are drawn to an apparatus for improving signal-to-noise in the detection of distinct target sequences, classified in class 435, subclass 288.7.

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- VII. Claims 151-169 are drawn to an apparatus for acquiring intact cytoplasmic biomolecules from cells, classified in class 435, subclass 287.2.
- VIII. Claims 170-177 are drawn to a kit for maintaining phenotypic and genotypic integrity of a single or population of cells, classified in class 435, subclass 307.1.
- IX. Claims 178-186 are drawn to a nucleotide amplification kit for increasing signal-to-noise ratio in distinct target sequences, classified in class 435, subclass 91.21.

The inventions are distinct, each from the other because of the following reasons:

#### DISTINCT PROCESSES

Inventions I, II, III, and IV are distinct processes. Inventions are distinct if the inventions as claimed are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in a materially different process) and wherein at least one invention is PATENTABLE (novel and nonobvious) OVER THE OTHER (though they may each be unpatentable over the prior art) (MPEP § 802.01). The processes are distinct from one another because they recite different and distinct steps which lead to different and distinct products.

#### DISTINCT APPARATUS

Inventions V, VI and VII are directed to distinct apparatus. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of

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operation, function, or effect. See MPEP § 806.05(j). In the instant case, the apparatuses are distinct from one another because they comprise distinct parts to perform different steps during their function.

#### DISTINCT PRODUCTS

Inventions VIII and IX are directed to distinct products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the two products do not overlap in scope since the product of group IX comprises distinct components that are unrelated to group VIII.

#### APPARATUS AND PROCESS

Inventions I and V are related as a process and an apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, common laboratory techniques, well known in the art can accomplish the method of group I instead of the apparatus of in claim V.

#### APPARATUS AND PROCESS

Inventions II and VI are related as a process and an apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the

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apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, common laboratory techniques, well known in the art can accomplish the method of group II instead of the apparatus of in claim VI.

#### APPARATUS AND PROCESS

Inventions III and VII are related as a process and an apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, common laboratory techniques, well known in the art can accomplish the method of group III instead of the apparatus of in claim VII.

#### DISTINCT PROCESSES AND APPARATUS

Inventions I and VI/VII are a distinct process and apparatus. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process of I cannot be performed by the apparatus of group VI or VII.

#### DISTINCT PROCESSES AND APPARATUS

Inventions II and V/VII are a distinct process and apparatus. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process of II cannot be performed by the apparatus of group V or VII.

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#### DISTINCT PROCESSES AND APPARATUS

Inventions III and V /VI are a distinct process and apparatus. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process of III cannot be performed by the apparatus of group V or VI.

#### DISTINCT PROCESSES AND APPARATUS

Inventions IV and V/VI/VII are a distinct process and apparatus. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process of IV cannot be performed by the apparatus of group V, VI or VII.

#### PRODUCT AND USE

Inventions I / III and VIII are related as a product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In this case, common laboratory techniques, well known in the art can accomplish the method of groups I or III instead of the kit in group VIII.

#### DISTINCT PRODUCTS OR PROCESSES

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Inventions II/IV and VIII are directed to unrelated products and processes. The inventions are distinct since they do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method steps of groups II and IV do not require the contents of the kit in group VIII.

#### PRODUCT AND USE

Inventions V/VII and VIII are related as a product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In this case, commercially available reagents could be used in the apparatus of groups V/VI instead of the kit in group VIII.

#### DISTINCT PRODUCTS OR PROCESSES

Inventions VI and VIII are directed to unrelated products and processes. The inventions are distinct since they do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the apparatus of group VI does not require the contents of the kit in group VIII.

#### DISTINCT PRODUCTS OR PROCESSES



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Inventions I/III/IV and IX are directed to unrelated products and processes. The inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the processes of groups I/III do not require the materials in the kit in group IX.

#### DISTINCT PRODUCTS OR PROCESSES

Inventions II and IX are directed to related products and processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the process of group II can be performed using commercially available reagents instead of those listed in group IX.

#### DISTINCT PRODUCTS AND APPARATUS

Inventions V/VII and IX are directed to unrelated product and apparatus. The inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the

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apparatus of group V or VII comprise different parts distinct from those listed in the kit in group IX.

#### APPARATUS AND USE

Inventions VI and IX are related as an apparatus and a process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the apparatus for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different apparatus using that product. See MPEP § 806.05(h). In the instant case, the apparatus of claim VI can use commercially available reagents other than those listed in the kit in group IX.

#### REASON FOR RESTRICTION

The several inventions listed above are independent and distinct from one another as they have acquired a separate status in the art and require independent searches, particularly with regard to the literature searches. A reference which would anticipate one of the above groups would not necessarily anticipate or even make obvious any of the others.

An undue burden would ensue from the examination of multiple methods which have distinct steps and end points. Burden lies not only in the search of US Patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, and distinctness.

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## ELECTION OF SPECIES

In addition to the election of an invention of group IX above, various elections of species must be made. This application contains claims containing the following patentably distinct species, which are described below.

If I is elected applicant should also elect ONE from each of the following groups below:

The applicant must elect one method for selecting the target cells listed in claim 3.

The applicant must elect one permeabilizing agent listed in either claims 6 or 7.

The applicant must elect one stabilizing agent from the following: aldehydes, urea, formaldehyde, paraformaldehyde, a dialdehyde, glutaraldehyde, and glyoxal.

The applicant must elect one agent for enzymatic digestion from the following: proteinases, nucleophiles, proteinase K digestion, V8 proteinase digestion, pronase digestion, phosphate-based buffers, tris-based buffers, acetic hydrazide, and hydroxylamine.

The applicant must elect one phenotypic expression assay from claim 26.

The applicant must elect one cytoplasmic biomolecule from a protein or nucleic acid.

If the applicant elects a protein an additional election of species must be made as described below:

The applicant must elect one separation method from claim 19.

The applicant must elect one method of analysis from functional proteomics or functional genomics.

If applicant elects functional proteomics, an additional election of one method of functional proteomics selected from the group listed in claim 28.

If applicant elects functional genomics, an additional election of one method of functional genomics selected from the group listed in claim 30.

If the applicant elects a nucleic acid an additional election of species must made as described below:

The applicant must elect one species of nucleic acid from the following: cytoplasmic RNA, nuclear and mitochondrial RNA, nuclear and mitochondrial DNA.

The applicant must elect one method of isolation of the nucleic acid from the following: RNA or DNA chemical extractions, electrophoresis, chromatography, immunoseparations, affinity techniques magnetic beads affixed to oligo(dT).

The applicant must elect one method of analysis from the following: Functional Genomics (encompassed in claims 29 and 30), multi-gene RT-PCR (encompassed in claim 31), genetic marker analysis

(encompassed in claims 32-40), or preamplification analysis  
(encompassed in claims 41-50).

If applicants elects functional genomics, an additional election of  
one method of functional genomics listed in claim 30.

If applicant elects genetic marker analysis, the applicant must  
elect the following:

The type of primer selected from those listed in claim 33

The method to accomplish high primer target annealing  
specificity selected from the options from the following:  
proteins from natural recombination cellular repair  
mechanisms and recA.

The sized-based analysis selected method listed in claim  
40.

If the applicant elects the preamplification method, the applicant  
must elect the following:

The type of primer used in the preamplification from the  
following: RNA polymerase using random primers, SP6  
RNA polymerase promoter, T3 RNA polymerase  
promoter, and T7 RNA polymerase promoter.

The method to accomplish high primer target annealing  
specificity selected from the options from the following:

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proteins from natural recombination cellular repair mechanisms and recA.

The pretreatment method selected from the group listed in claim 48.

The method of recognizing the amplified product selected from the following: DNase-free Rnases, phenol extraction and silica binding.

If II is elected applicant should also elect ONE from each of the following groups below:

The applicant must elect one type of nucleic acid selected from the following: cytoplasmic RNA, nuclear and mitochondrial RNA, nuclear and mitochondrial DNA, and cytoplasmic mRNA.

The applicant must elect one type of isolation method selected from the following: RNA or DNA chemical extractions, electrophoresis, chromatography, immunoseparations, affinity techniques and magnetic beads affixed to oligo(dT).

The applicant must elect one means of purification of nucleic acid selected from the group listed in claim 62.

The applicant must elect one type of primer for preamplification selected from the following: RNA polymerase using random primers, SP6 RNA polymerase/promoter, T3 RNA polymerase/promoter, and T7 RNA polymerase/promoter.

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The applicant must elect one method to accomplish high primer target annealing specificity selected from the following: proteins from natural recombination cellular repair mechanisms and recA.

The applicant must elect one method of identifying the target sequence selected from the following: amplification of all double-stranded products, array analysis, and electrophoresis.

If III is elected applicant should also elect ONE from each of the following groups below:

The applicant must elect one stabilizing agent selected from the following: aldehydes, urea, formaldehyde, paraformaldehyde, a dialdehyde, glutaraldehyde, glyoxal.

The applicant must elect one agent for enzymatic digesting selected from the following: proteinases, nucleophiles, proteinase K digestion, V8 proteinase digestion, pronase digestion, phosphate-based buffers, tris-based buffers, acetic hydrazide, hydroxylamine.

The applicant must elect one cytoplasmic biomolecule from a protein or nucleic acid.

If the applicant elects a protein an additional election of species must be made as described below:

The applicant must elect one recovery method selected from the group listed in claim 77.

If the applicant elects a nucleic acid an additional election of species must

be made as described below:

The applicant must elect one species of nucleic acid selected from the following: cytoplasmic RNA, nuclear and mitochondrial RNA, nuclear and mitochondrial DNA, and cytoplasmic mRNA.

The applicant must elect one method of analysis selected from the following: RNA or DNA chemical extractions, electrophoresis, chromatography, immunoseparations, affinity techniques and magnetic beads affixed to oligo(dT).

If IV is elected applicant should also elect ONE from each of the following groups below:

The applicant must elect one method to remove gene specific primers selected from the following: molecular size exclusion, solid support selective attachment, single strand specific DNase, and incorporating uracil-N-glycosylase with DNA oligonucleotide primers synthesized with deoxyuridine.

The applicant must elect one method to accomplish high primer target annealing specificity from the following: proteins from natural recombination cellular repair mechanisms and recA.

The applicant must elect one method of size-based analysis selected from the group listed in claim 91.

If V is elected applicant should also elect ONE from each of the following groups below:



The applicant must elect one means to obtain a fluid sample selected from the following: immunomagnetic selection means and cell fractionation means.

The applicant must elect one permeabilizing agent selected from the following: saponin and Immuniperm.

The applicant must elect one stabilizing agent from the following: aldehydes, urea, formaldehyde, paraformaldehyde, a dialdehyde, glutaraldehyde, glyoxal.

The applicant must elect one agent for enzymatic digesting selected from the following: proteinases, nucleophiles, proteinase K digestion, V8 proteinase digestion, pronase digestion, phosphate-based buffers, tris-based buffers, acetic hydrazide, hydroxylamine.

The applicant must elect one phenotypic expression assay selected from the following: morphological examining means, cell component staining means, and immunoanalyzing means.

The applicant must elect one cytoplasmic biomolecule from a protein or nucleic acid.

If the applicant elects a protein an additional election of species must be made as described below:

The applicant must elect one isolation method from claim 110.

The applicant must elect one method of analysis from functional proteomics or functional genomics.

If applicants elects functional proteomics, an additional election of one method of functional proteomics selected from the following: protein expression profile means, Western blot means, amino acid sequence analysis means, electrophoresis means, 2-D electrophoresis means, mass spectrometry means, gas chromatography means, liquid chromatography means, nuclear magnetic resonance means, infrared means, and atomic adsorption means.

If applicants elects functional genomics, an additional election of one method of functional genomics listed in claim 121.

If the applicant elects a nucleic acid an additional election of species must made as described below:

The applicant must elect one species of nucleic acid from the following: cytoplasmic RNA, nuclear and mitochondrial RNA, nuclear and mitochondrial DNA, and cytoplasmic mRNA.

The applicant must elect one method of isolation of the nucleic acid from the following: RNA or DNA chemical extractions, electrophoresis, chromatography, immunoseparations, affinity techniques and magnetic beads affixed to oligo(dT).

The applicant must elect one method of analysis from the following: Functional Genomics (encompassed in claims 120 and 121), multi-gene RT-PCR (encompassed in claim 122), genetic marker analysis

(encompassed in claims 123-131), or preamplification analysis  
(encompassed in claims 132-134).

If applicants elects functional genomics, an additional election of  
one method of functional genomics listed in claim 121.

If applicant elects genetic marker analysis the applicant must  
elect the following:

The applicant must elect one means to removed gene  
specific primers selected from the following: molecular  
size exclusion, solid support selective attachment, single  
strand specific DNase, and incorporating uracil-N-  
glycosylase with DNA oligonucleotide primers  
synthesized with deoxyuridine and Dnase-free RNases.  
The method to accomplish high primer target annealing  
specificity selected from the following: proteins from  
natural recombination cellular repair mechanisms and  
recA.

The sized-based analysis selected method listed in claim  
131.

If the applicant elects the preamplification method the applicant  
must elect the following:

For claim 132 step c, the applicant must elect one  
between a means for recognizing an amplified product

selected from the group listed from an array analysis or electrophoresis means.

The type of primer used in the preamplification from the following: RNA polymerase using random primers, SP6 RNA polymerase promoter, T3 RNA polymerase promoter, and T7 RNA polymerase promoter.

If VI is elected applicant should also elect ONE from each of the following groups below:

The applicant must elect one type of nucleic acid selected from the following: cytoplasmic RNA, nuclear and mitochondrial RNA, nuclear and mitochondrial DNA, and cytoplasmic mRNA.

The applicant must elect one type of isolation method selected from the following: RNA or DNA chemical extractions, electrophoresis, chromatography, immunoseparations, affinity techniques and magnetic beads affixed to oligo(dT).

The applicant must elect one means of purification of nucleic acid selected from the following: DNase-free Rnases means phenol extraction means, and silica binding means.

The applicant must elect one type of primer for preamplification selected from the following: RNA polymerase using random primers, SP6 RNA polymerase promoter, T3 RNA polymerase promoter, and T7 RNA polymerase promoter.

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The applicant must elect one method for high primer-target annealing specificity selected from the following: proteins from natural recombination cellular repair mechanisms and recA.

The applicant must elect one means to identify the target sequence selected from the following: amplification of all double-stranded products, array analysis, and electrophoresis.

If VII is elected applicant should also elect ONE from each of the following groups below:

The applicant must elect one stabilizing agent from the following: aldehydes, urea, formaldehyde, paraformaldehyde, a dialdehyde, glutaraldehyde, glyoxal.

The applicant must elect one agent for enzymatic digesting means from the following: proteinases, nucleophiles, proteinase K digestion, V8 proteinase digestion, pronase digestion, phosphate-based buffers, tris-based buffers, acetic hydrazide, hydroxylamine.

The applicant must elect one cytoplasmic biomolecule from a protein or nucleic acid.

If the applicant elects a protein an additional election of species must be made as described below:

The applicant must elect one recovery method from claim 164.

If the applicant elects a nucleic acid an additional election of species must be made as described below:

The applicant must elect one species of nucleic acid from the following:  
cytoplasmic RNA, nuclear and mitochondrial RNA, nuclear and  
mitochondrial DNA, and cytoplasmic mRNA.

The applicant must elect one method of analysis from the following:  
RNA or DNA chemical extractions, electrophoresis, chromatography,  
immunoseparations, affinity techniques and magnetic beads affixed to  
oligo(dT).

If VIII is elected applicant should also elect ONE from each of the following  
groups below:

The applicant must elect one permeabilizing agent selected from the  
following: saponin and Immuniperm.

The applicant must elect one stabilizing agent listed in claims 174.

The applicant must elect one releasing agent selected from the  
following: proteinases, nucleophiles, proteinase K digestion, V8  
proteinase digestion, pronase digestion, phosphate-based buffers, tris-  
based buffers, acetic hydrazide, hydroxylamine.

If IX is elected applicant should also elect ONE from each of the following  
groups below:

The applicant must elect one isolating agent selected from the  
following: immunomagnetic particles, RNA or DNA chemical extracting  
agents, electrophoresis agents, chromatography agents,  
immunoseparation agents and nucleotide affinity agents.

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The applicant must elect one preamplifying agent selected from the following: RNA polymerase using random primers, SP6 RNA polymerase promoter, T3 RNA polymerase promoter, and T7 RNA polymerase promoter.

The applicant must elect one purifying agent selected from the group listed in claims DNase-free Rnases, phenol extraction agents, and silica binding agents.

The applicant must elect one detecting agent selected from the group listed in claim 186.

The species are independent or distinct because they do not belong to any art recognized group nor do they share a substantial structural feature. Art on one species does not render the others obvious.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 51, 65, 83, 92, 135, 151, 170, and 178 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and **a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

#### MULTIPLE INVENTORS

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### OCHIAI

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the



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patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

CONCLUSION

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

#### CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached during regular business hours, 8:00 to 17:00 EST.

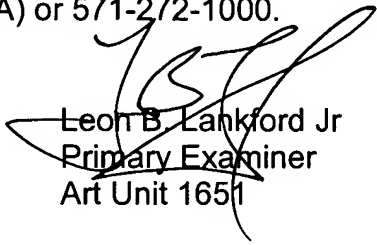
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1651



Leon B. Lankford Jr  
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Art Unit 1651